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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,557

02/10/2004

Peter Nash

C150.12.4

1455

7590

01/12/2007

Richard O. Bartz
Suite 350
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Edina, MN 55435

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

01/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/775,557

Applicant(s)

NASH ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Vacation of Previous Office Action

1. Applicant is advised that the office action of October 6, 2006 is vacated.

Claims 1-48 are under consideration in this office action.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-14 and 42-48 are drawn to a microbial adherence inhibitor for administration to animals to substantially prevent the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals and a method of producing a microbial adherence inhibitor for administration to a human to inhibit the adherence of targeted colony-forming immunogens in the respiratory tracts of said humans, classified in class 424, subclass 184.1.
- II. Claims 15-19 are drawn to a microbial adherence inhibitor for administration to food animals substantially preventing the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals comprising egg contents incorporating antibody specific to said targeted colony-forming immunogens, classified in class 424, subclass 130.1.
- III. Claims 20-25 are drawn to a microbial adherence inhibitor for promoting the growth of food animals by decreasing the respiratory

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stress caused by the presence of a colony-forming immunogen in the respiratory tract of the animal by inhibiting the ability of the colony-forming immunogen to adhere to the respiratory tracts of food animals to reduce the ability of the colony-forming immunogen to multiply, said colony-forming immunogen Porcine Reproduction and Respiratory Syndrome produced by the instantly claimed method classified in class 424, subclass 278.1.

- IV. Claims 26-41 are drawn to a method for decreasing animal respiratory illness by inhibiting the ability of a targeted colony-forming immunogen to adhere to the respiratory tract of an animal to reduce the ability of the immunogen to multiply wherein the immunogen is from the class of respiratory bacterium or viruses, classified in class 435, subclass 252.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and any of II-IV are related as different products. The products are distinct as claimed because they have different structures and different uses. Group II is drawn to a microbial adherence inhibitor which comprises egg contents that incorporates antibody specific to said targeted colony-forming immunogens; while group III is drawn to a microbial adherence inhibitor for promoting the growth of food animals by decreasing the respiratory stress by inhibiting the ability of the Porcine Reproduction and Respiratory Syndrome colony-forming immunogen to adhere to the respiratory tracts of food

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animals to reduce the ability of the immunogen to multiply. Each product has a different function, effect and is capable of use without the other. For instance, only Group III is drawn to a microbial adherence inhibitor for promoting the growth of food animals by decreasing the respiratory stress, while the other groups are drawn to inhibitors with different abilities.

Furthermore the Inventions are related as distinct methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. The methods of producing or using the inhibitors are different. For instance, only Group III is drawn to a method for decreasing an animal's respiratory illness by mixing the separated contents of the harvested egg and administering the mixed contents to an animal whereby the antibody to the immunogen inhibits adherence of the immunogen. The method of Group I has a different function, to produce a method of producing a microbial adherence inhibitor for administration to a human to inhibit the adherence of targeted colony-forming immunogens in the respiratory tracts of said humans, which is a entirely different method. The method of group I does not produce the same results as Group III. Each group produces different effects and different functions when compared to the other group. Therefore, the inventions are unrelated.

Additionally, searching the inventions of groups I and any of II-IV together would impose a serious search burden. In the instant case, the search of the inhibitors, methods of production, and methods for decreasing animal respiratory

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illness are not coextensive. The inventions of Groups I, II, III and IV have a separate status in the art as shown by their different classifications. Thus the product and method of production of Group I requires a different search than the method for decreasing animal respiratory illness. Searching for a method for decreasing an animals respiratory illness by mixing the separated contents of the harvested egg and administering the mixed contents to an animal whereby the antibody to the immunogen inhibits adherence of the immunogen is not necessary for a determination of novelty and unobviousness of the product of Group I. Moreover, a search of Group I is not required to identify the product of Group II. Only group IV requires a search for a method for decreasing animal respiratory illness by inhibiting the ability of a targeted colony-forming immunogen to adhere to the respiratory tract of an animal to reduce the ability of the immunogen to multiply wherein the immunogen is from the class of respiratory bacterium or viruses. In addition, the technical literature search for the product of Group I and the product of Group II are not coextensive, e.g., the product of Group I may be characterized in the technical literature prior to discovery of the product of Group II. Accordingly, searching the inventions of Groups I, II, III and IV together would impose a serious search burden.

3. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-IV together.

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4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

4. The following is drawn to the species election.

1) Claims 1-12, 42-48 of group I are generic to a plurality of disclosed patentably distinct species comprising:

A) Claims 13 and 14 recite that said targeted colony-forming immunogens are from the class of respiratory viruses including swine influenza (H1N 1, H3N2), bovine respiratory syncytial virus (BRSV), bovine viral diarrhea (BVD), bovine parainfluenza3 (BPI3), and infectious bovine rhinotracheitis (IBR) viruses.

Therefore a single virus should be selected.

2) Claims 15 and 18 of group II are generic to a plurality of disclosed patentably distinct species comprising:

B) Claims 17 and 19 recite that said targeted colony-forming immunogens are from the class of respiratory viruses including swine influenza (H1N 1, H3N2), bovine respiratory syncytial virus (BRSV),

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bovine viral diarrhea (BVD), bovine parainfluenza3 (BPI3), and infectious bovine rhinotracheitis (IBR) viruses.

Therefore a single virus should be selected and the appropriate claim will be examined.

3) Claims 26 and 31-37 of group IV are generic to a plurality of disclosed patentably distinct species comprising:

C) Claims 27-28 and 38-39 recite that said targeted colony-forming immunogens are from the class of respiratory bacteria including *Mycoplasma pieuropneumoniae*, *Mycoplasma hypopneumoniae*, and *Mycoplasma bovis*, *Pasteurella multocoda*, *M. haemolytica*, *Haemophilus somnus* and *Haemophilus suis*.

D) Claims 29-30 and 40-41 recite that said targeted colony-forming immunogens are from the class of respiratory viruses including swine influenza (H1N 1, H3N2), bovine respiratory syncytial virus (BRSV), bovine viral diarrhea (BVD), bovine parainfluenza3 (BPI3), and infectious bovine rhinotracheitis (IBR) viruses.

Therefore a single bacterial or viral species should be selected.

Therefore, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 7, 2007

